SEP 1 3 2001

510(k) Summary

Prepared June 1, 2000

K001687

1. Submitter Information

Chromatics Color Sciences International, Inc.
5 East 80th Street
New York, New York 10021-0109
212-717-6544

2. Contact Person

Thomas M. Tsakeris, President
Devices & Diagnostics Consulting Group, Inc.
16809 Briardale Road
Rockville, MD 20855
301-330-2076

3. Device Information

ColorMate® TLc•BiliTest® System
Noninvasive Transcutaneous Bilirubinometer
Bilirubin (total and unbound) in the neonate test system (21 C.F.R. § 862.1113)
Class I
Product Code MQM

4. Predicate Device

ColorMate III (K964590)

5. Description of Device

The ColorMate® TLc•BiliTest® System [originally the ColorMate III] was cleared under 510(k) K964590. The device is a computer-assisted, non-invasive transcutaneous bilirubinometer, which through colormetric technology, illuminates the skin of newborn babies and measures the yellow content of the skin color. The incremental changes of these color readings measured over time are compared to the newborn's baseline ColorMate® TLc•BiliTest® System readings. The data are then automatically processed to provide the numerical index of predicted bilirubin count that has been shown to correlate with total serum bilirubin concentration within a clinical useful range.

The ColorMate® TLc•BiliTest® System is generically composed of a computer system, a colormetric sensor, a data cable, an optional data printer, a calibration standard, and a verification standard. Additionally, the computer system has an optional modem which enables transmission of data from one ColorMate® TLc•BiliTest® System to another or to a server.

6. Indications for Use

The ColorMate® TLc•BiliTest® System is indicated to be used as an aid to the physician in monitoring the status of newborn babies for the development of hyperbilirubinemia. Following the physician's examination within the first hours of birth, newborn babies are initially measured and periodically monitored by the TLc•BiliTest® System for incremental changes in the yellow content of the skin color as compared to the baseline TLc•BiliTest® System measurements. Babies with TLc•BiliTest® System test results indicative of hyperbilirubinemia are to be re-evaluated by the attending physician for appropriate patient management.

7. Technological Characteristics

This 510(k) Premarket Notification addresses the Company's intent to commercially distribute its ColorMate® TLc•BiliTest® System with the following modifications:

- Offer for sale to the hospital/clinician a dedicated server for storing and accessing patient data whereby the data are set up for access by authorized health care providers by transferring the data to the server via the Internet (with an encryption code).

- Offer for sale the ColorMate®'s software and color sensor as a standalone system, to be used with any hospital's/clinician's computer system meeting defined specifications.

- Revise the labeling and software to adjust the current requirement that a baseline skin reading must be obtained within 30 hours of birth to a more conservative time of within 12 hours of birth.

- Revise the "Limitations of Test" section in the operator manual to state that babies born with clinically significant jaundice or born very prematurely with underdeveloped (partially transparent) skin should not be monitored with the device.

The "indications for use," "intended use" and principles of operation are unchanged from the original ColorMate III 510(k). The modified system has passed UL 2601-1 testing and has received UL certification. Other changes were made to the device, for among other reasons, to:

- Make the system more portable, as well as easier and more convenient to use.

- Eliminate features, which although useful in conducting the clinical trials presented in support of the original ColorMate III 510(k), were not necessary for commercial versions of the device.

- Expand the capability of the device to transmit, store, and retrieve patient information.

8. Performance Data

The product modifications were amenable to non-clinical study testing. Routine verification and validation activities were executed on the modifications. Specifically, with respect to software changes, Chromatics substantially followed the recommended testing and other steps found in the Food and Drug Administration's guidance document entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The data from these activities establish that the ColorMate® TLc•BiliTest® System is as safe and effective as the original ColorMate III and performs as well as or better than the ColorMate III.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Chromatics Color Sciences International, Inc.
c/o Mr. Thomas M. Tsakeris
Regulatory Consultant
Devices and Diagnostics Consulting Group. Inc.
16809 Briardale Road
Rockville, MD 20855

SEP 1 3 2001

Re: k001687
Trade/Device Name: Colormate® TLc•BiliTest® System
Regulation Number: 21 CFR 862.1113
Regulation Name: Bilirubin (total and unbound) in the neonate test system
Regulatory Class: Class I, Reserved
Product Code: MQM
Dated: May 7, 2001
Received: May 7, 2001

Dear Mr. Tsakeris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CONFIDENTIAL

Indications For Use

K001687

Device Name: Colormate® TLc•BiliTest® System

Indications For Use:

The ColorMate® TLc•BiliTest® System is indicated to be used as an aid to the physician in monitoring the status of newborn babies for the development of hyperbilirubinemia. Following the physician's examination within the first hours of birth, newborn babies are initially measured and periodically monitored by the TLc•BiliTest® System for incremental changes in the yellow content of the skin color as compared to the baseline TLc•BiliTest® System measurements. Babies with TLc•BiliTest® System test results indicative of hyperbilirubinemia are to be re-evaluated by the attending physician for appropriate patient management.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter:
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Kevin Alexander for Joan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001687